

REMARKS

In the final Office Action mailed January 9, 1998, claims 45,46, and 48 were allowed, and claims 33-37, 39, 40-44 and 47 were rejected. Applicants hereby request amendment of rejected claims 33-34, 36, and 40, and further request amendment of allowed claims 45 and 46. A Notice of Appeal is being concurrently filed.

The amendments to allowed claims 45 and 46 narrow the scope of claims 45 and 46, and these amendments therefore require no additional search or examination. Specifically, the definition for the R₅ substituent has been amended to exclude hydrogen when R' and R" represent H, OH, C₁-C₄ alkoxy or C₁-C₄ acyloxy, in addition to the previously existing proviso in the definition that R₅ cannot be hydrogen if R' and R" taken together form an oxo or a methano. Nonetheless, even including the additional limitations, these generic compound claims continue to cover the compounds disclosed on pp. 16-22 of the specification. Accordingly, the amended claims remain patentable and applicants respectfully request entry of the proposed amendments to claims 45 and 46.

Rejected claims 33-34, 36, and 40 have been amended to expressly state that the specified first compound in each claim, which compound selectively activates Retinoid X Receptors in preference to Retinoic Acid Receptors, is more potent an activator of a Retinoid X Receptor than all of Retinoic Acid Receptor isoforms α , β , and γ . The support for this amendment is found in the specification e.g., in the examples of Tables 1, 2, and 3 on pages 73, 74-75, 76, and 77 of the specification, which show that the specified compounds are more potent activators of a Retinoid X Receptor than of each and all of the Retinoic Acid Receptor isoforms α , β , and γ . This amendment is made to clarify and remove any possible ambiguity that the specified RXR selective compounds

do not include compounds such as, e.g., 9-cis-retinoic acid and the Maignon Ex. II compound discussed and shown on pages 76-78 of the specification.

Since these amendments to claims 33-34, 36, and 40 merely clarify and either narrow or do not change the scope of the claims, the proposed amendments require no additional search or examination. It is further believed that these amendments place the rejected claims in better form for consideration on appeal. Accordingly, entry of the proposed amendments to claims 33-34, 36, and 40 is respectfully requested.

Claims 33-37, 39, 40-44 and 47 have been rejected under 35 U.S.C. §112, paragraph 2, as being overly broad. The examiner has stated the claims should be limited to a generic (structural) disclosure as recited and set forth in the specification. Applicants do not agree that these claims are overly broad, and respectfully traverse this basis for rejection.

“A claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial structure is presented...A compound of unknown structure may be claimed by a combination of physical and chemical characteristics.” MPEP § 2173.05 (t).

Applicants are entitled to claims drawn as broadly as the prior art will allow provided the subject matter is adequately disclosed and distinctly claimed. Limiting claims 33-37, 39, 40-44 and 47 to a generic structure when the claims adequately define the subject matter and scope of the invention unduly limits the invention and is not warranted when the prior art does not disclose the compounds or activity that the compounds are disclosed as possessing. See, MPEP § 2173.04.

Section 112, second paragraph, requires the claims define “the subject matter which the applicant regards as his invention.” This means that an applicant is required to set definite boundaries on the patent protection sought. When there are adequate boundaries defining the invention, broad claims cannot be equated with indefiniteness. MPEP § 2173.04. Also, see *e.g.*, In re Gardner, 166 U.S.P.Q. 138, 140 (CCPA 1970) (“Breadth is not indefiniteness.”); In re Wakefield, 422 F.2d 897, 164 U.S.P.Q. 636, 641 (CCPA 1970) (A large number of substances were encompassed by a set of claims, but the scope of the claims was still definite, because each recited limitation was definite.); In re Hyatt, 218 U.S.P.Q. 195, 197 (Fed. Cir. 1983) (If the scope of subject matter embraced by a claim is clear, then a claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.) Under Section 112, second paragraph, if those skilled in the art can tell whether any particular compound is or is not within scope of a claim, the claim fulfills its purpose as a definition. See, *e.g.*, In re Miller, 169 U.S.P.Q. 597, 599 (CCPA 1971) (“if those skilled in the art can tell whether any particular PTFE powder is or is not within the scope of a claim, the claim fulfills its purpose as a definition.”)

A claim should not be denied solely because of the type of language used to define the subject matter. See *e.g.*, In re Miller, 169 U.S.P.Q. 597, 599 (CCPA 1971); MPEP §§ 2173.01-.02. Applicants have amended the term previously objected to, “ligand,” to the term “compound.” The claims cannot be considered overly broad or indefinite as the scope of the term “compound” is defined throughout the specification and the compounds useful in the invention and the methods for identifying the compounds of the invention are described throughout the specification. An intelligible term in a claim, defined throughout the specification, is not indefinite. See *e.g.*, In re

Farrow, 193 U.S.P.Q. 689 (CCPA 1977) (A term commented on by the Examiner was intelligible to the Examiner and not indefinite.).

For example, pp. 67-72 of the specification describes a co-transfection assay which can be used to evaluate the retinoid receptor subtype selectivity of a compound to determine whether a compound is one possessing the desired activity, as specified in applicants' claims 33-37 and 39-44. For example, the specification discloses compounds including 3-Methyl-TTNCB and 3-Methyl-TTNEB as compounds which preferentially activate RXR's in preference to RAR's. In addition, the compound all-trans-retinoic acid is identified as a ligand upon which the transcription -modulating activity of RAR-alpha depends and all-cis-retinoic acid is described as a natural endogenous ligand for retinoid X receptors, which is able to bind and transactivate both RXRs and RARs (a bifunctional ligand). "Where the invention resides in finding the activity rather than in discovering some critical range or the like, we have approved of such broad definitions ..." In re Gardner, 166 USPQ 138, 140 (CCPA 1970). The specification also discloses the greater than additive effect of combining two different types of ligands together. See, for example, pp. 89-96 of the specification.

Applicants therefore submit that claims 33-37, 39, 40-44 and 47 adequately define the claimed invention and when read in context with the specification adequately define the scope of what applicants regard as their invention (i.e., the boundaries of the invention are adequately defined in the claims). Applicants have disclosed compounds which possess the specified activity, and do not seek to claim an indefinite group of compounds, only those which possess the desired activity. Applicants are entitled to claims drawn as broadly as the prior art will allow, and, as noted above, breadth alone does not make a claim "indefinite". See also, MPEP § 2173.04.

Further, method claim 40 has been previously amended to incorporate and specify the specific disease states modulated by the claimed methods of using the specified compounds as an additional definite limitation on this claim and its dependent claims. This previous amendment further clarified and defined the invention of claim 40.

Accordingly, applicants respectfully submit that believe claims 33-37, 39, 40-44 and 47 in addition to allowed claim 45,46, and 48 are in condition for allowance and applicants request reconsideration of all rejected claims.

Respectfully submitted,

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